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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/909,567 | 07/20/2001 | Roberto A. Macina | DEX-0214 | 4354 |

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LICATLA & TYRRELL P.C.
66 E. MAIN STREET
MARLTON, NJ 08053

| EXAMINER |
|---|
| MARSCHEL, ARDIN H |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

DATE MAILED: 07/31/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/909,567 | MACINA ET AL. | |
| | Examiner | Art Unit | |
| | Ardin Marschel | 1631 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to an LSG which is either a polynucleotide or a polypeptide , classified in class 536 and 530, subclass 23.1 and 300, respectively. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then the below summarized specie election is also required.

II. Claim 3, drawn to diagnosis of the presence of lung cancer in a patient, classified in class 435, subclasses 6 and 7.1. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then the below summarized specie election is also required.

III. Claims 4-7, drawn to diagnosis or staging of metastases or cancer regression or remission regarding lung cancer in a patient, classified in class 435, subclasses 6 and 7.1. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then the below summarized specie election is also required.

IV. Claim 8, drawn to identification of potential therapeutic agents for use in imaging and treating lung cancer, classified in class 514, subclasses 1, 2,

or 44. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then the below summarized specie election is also required.

V. Claims 9 and 10, drawn to antibodies, classified in class 530, subclass 387.1. If this Group is elected then the below summarized sequence election is also required.

VI. Claims 11 and 12, drawn to imaging lung cancer via antibody administration, classified in class 435, subclass 4. If this Group is elected then the below summarized sequence election is also required.

VII. Claim 13, drawn to a method of treating lung cancer utilizing a compound which downregulates expression or activity of an LSG, classified in class 514, subclasses 1, 2, or 44. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then the below summarized specie election is also required.

VIII. Claims 14 and 15, drawn to a method of inducing an immune response via polypeptide delivery to a human patient, classified in class 424, subclass 184.1. If this Group is elected then the below summarized sequence election is also required.

IX. Claim 16, drawn to an LSG vaccine, classified in class 424, subclass 184.1. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then the below summarized specie election is also required.

**Sequence Election Requirement Applicable to All Groups:**

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid/polypeptide sequences, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

**SPECIE ELECTION REQUIREMENT FOR GROUPS I – IV, VII, AND IX:**

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: an LSG which is a polynucleotide

Specie B: an LSG which is a polypeptide

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims in Groups I – IV, VII, and IX are generic to the above species. This distinctness or independence of polynucleotides versus polypeptides is described below.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups [I(polynucleotide specie), II(polynucleotide specie), III(polynucleotide specie), IV(polynucleotide specie), VII(polynucleotide specie), and IX(polynucleotide specie)]; Groups [I(polypeptide specie), II(polypeptide specie), III(polypeptide specie), IV(polypeptide specie), VII(polypeptide specie), VIII, and IX(polypeptide specie)]; and Groups (V and VI) are independent inventions because they are directed to different chemical types regarding the critical limitations therein. For Groups [I(polypeptide specie), II(polypeptide specie), III(polypeptide specie), IV(polypeptide specie), VII(polypeptide specie), VIII, and IX(polypeptide specie)] the critical feature is a polypeptide; for Groups [I(polynucleotide specie), II(polynucleotide specie), III(polynucleotide specie), IV(polynucleotide specie), VII(polynucleotide specie), and IX(polynucleotide specie)] the critical feature is a polynucleotide; and for Groups V and VI; the critical feature is an antibody. It is acknowledged that various processing steps may cause a polypeptide of Groups [I(polypeptide specie), II(polypeptide specie), III(polypeptide specie), IV(polypeptide specie), VII(polypeptide specie), VIII, and IX(polypeptide specie)] to be directed as to its synthesis by a polynucleotide of Groups [I(polynucleotide specie), II(polynucleotide specie), III(polynucleotide specie), IV(polynucleotide specie), VII(polynucleotide specie), and IX(polynucleotide specie)], however, the completely separate chemical types of the inventions of the polynucleotide, polypeptide, and antibody Groups supports the undue search burden if both were examined together. Additionally, polynucleotides, polypeptides, and

antibodies have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together as compared to being searched separately. Also, it is pointed out that processing that may connect two Groups does not prevent them from being viewed as distinct because enough processing can result in producing any composition from any other composition if the processing is not limited as to additions, subtractions, enzyme action, etc. Thus, the three Groupings [I(polynucleotide specie), II(polynucleotide specie), III(polynucleotide specie), IV(polynucleotide specie), VII(polynucleotide specie), and IX(polynucleotide specie)]; [I(polypeptide specie), II(polypeptide specie), III(polypeptide specie), IV(polypeptide specie), VII(polypeptide specie), VIII, and IX(polypeptide specie)]; and (V and VI) are independent and/or distinct invention types for restriction purposes.

The inventions Groupings [I(polynucleotide specie), II(polynucleotide specie), III(polynucleotide specie), IV(polynucleotide specie), VII(polynucleotide specie), and making of the vaccine of IX(polynucleotide specie)] are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the LSG polynucleotide species of Group I may be utilized in the distinct usages as summarized in Groupings II(polynucleotide specie), III(polynucleotide specie), IV(polynucleotide specie), VII(polynucleotide specie), and making the vaccine of IX(polynucleotide specie), or, alternatively, for expression of polypeptides for study,

preparation of antibodies, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

The distinctness of the methods of Groupings II(polynucleotide specie), III(polynucleotide specie), IV(polynucleotide specie), VII(polynucleotide specie), and the making of the vaccine of IX(polynucleotide specie)] have been summarized in the above paragraph. It is noted that the intended usage of Group IX as a vaccine is also clearly distinct from the other above listed usages.

The inventions of Groupings [I(polypeptide specie), II(polypeptide specie), III(polypeptide specie), IV(polypeptide specie), VII(polypeptide specie), VIII, and the making of the vaccine of IX(polypeptide specie)] are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide species of Group I can be utilized in the distinct usages of the methods of Groups II(polypeptide specie), III(polypeptide specie), IV(polypeptide specie), VII(polypeptide specie), VIII, and the making of the vaccine of IX(polypeptide specie)], or, alternatively, for polypeptide activity study or the preparation of antibodies, for example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack

of overlapping searches documents the undue search burden if they were searched together.

The distinctness of the methods of Groupings II(polypeptide specie), III(polypeptide specie), IV(polypeptide specie), VII(polypeptide specie), VIII, and the making of the vaccine of IX(polypeptide specie)] have been summarized in the above paragraph. It is noted that the intended usage of Group IX as a vaccine is also clearly distinct from the other above listed usages.

The inventions Group V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group V may be utilized in several distinct usages, including the invention of Group VI, immunoassays, and antibody therapy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 30, 2002

ARDIN H. MARSCHEL
PRIMARY EXAMINER